New Hampshire Department of Environmental Services

Quality Assurance System

Guidance on Annual Program Self-Assessments

October 2003

This document is intended to help program managers fulfill the Annual QA Program Self-Assessment requirements as outlined in the DES Quality Management Plan. Members of the QA Team, who are identified on the DES Intranet under "Quality Assurance at DES," can help address any challenges or concerns raised during the QA System implementation process.

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1. Introduction to the DES Quality Assurance System

The mission of the New Hampshire Department of Environmental Services (DES) is to help maintain a high quality of life for all citizens by protecting and restoring the environment and public health in New Hampshire. In carrying out its mission, DES relies upon many different types of data that enable it to better evaluate and measure existing environmental conditions, to identify and understand areas of concern, to assign responsibility for these areas, and to promote and enhance credible communication on environmental issues to a wide variety of audiences.

The data DES uses must be credible, and the quality of that data must be appropriate for its intended uses. The Department, through its Quality Assurance (QA) System is moving towards a more systematic approach to the management of data and overall quality assurance issues across DES.

To accomplish this, every DES staff member must understand how his or her activities affect data quality issues, and all staff must know what they have to do to help produce quality data. This is accomplished by having a central documented plan, which is periodically reviewed and updated so that the overall data QA System continuously improves.

Implementation of the DES Quality Management Plan is the responsibility of staff throughout the Department, with the guidance and support of the DES Senior Leadership Team, the QA Manager and QA Team, as well as program managers.

The DES QA System is intended to ensure that program managers generate, review, and transmit data that has the appropriate quality for the intended uses. It follows established management principles of "Plan-Do-Check-React" or Total Quality Management, as taught by Deming and many others.

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2. Definitions

Audit

A systematic examination to determine whether quality activities and related results comply with planned arrangements and whether the arrangements are implemented effectively and are suitable to achieve objectives.

Audit, 1st Party

An audit conducted by members of the organization being audited. The annual self-assessments required in the DES Quality Management Plan are 1st party audits.

Audit, 2nd Party

An audit conducted by individuals from within the same corporate body as the organization being audited, but who are not entirely independent of the organization. These are generally considered superior to 1st party audits due to a higher degree of separation. An audit of a program's quality system by the DES QA Team is an example of a 2nd party audit.

Audit, 3rd Party

An audit conducted by individuals from an organization which is entirely independent from the organization being audited. ISO 9000 and 14001 registration audits, and audits of DES by EPA are examples of 3rd party audits.

Document

Any written, recorded information that is subject to change over time. Procedures, plans, policies, and records are documents. Documents may be controlled. See Records.

Documented Procedure

A written document that details the method for an operation, analysis, or action with thoroughly prescribed techniques and steps, and that is officially approved as the method of performing certain routine or repetitive tasks. Often in the form of a memo. This memo may simply document reliance on a standard reference, such as *Standard Methods for the Examination of Water and Wastewater.*

Program

A functional unit of the DES conducting a program defined in statute(s) or otherwise, for example in the DES Strategic Plan. This administrative function will often be found at the Bureau level, but this varies across DES. An example would be the Limnology Center Program within the Watershed Management Bureau of the Water Division.

Program Manager

The person responsible for conducting a specific DES program. This program management function is vested in staff at different administrative levels within DES.

Project Manager

The person that has direct knowledge and/or responsibility at the project or site-specific level.

Records

A completed document that provides objective evidence of an item or process. Records, which are documents not subject to change over time, include photographs, drawings, magnetic tape, or other data recording media. See documents.

3. 1st Party Auditing in the DES QA System – *the Condensed Version*

This Guidance focuses on the "Check" part of the DES QA System. This revision of the Guidance has been prepared especially to help program managers with the required calendar year 2003 QA System Program Self-Assessment, which is due on January 31, 2004. Please see the November, 2001 ***Implementation Guidance for Program Managers*** for summary information on the entire DES QA System (available online at http://intranet/qa/qmpguidance.pdf). Fundamentally, program managers are responsible to explicitly check, at least annually, whether the work went as expected, what problems were encountered, whether procedures still meet program needs, and where improvements can be made.

This checking process is where program managers begin to *manage* the process, and is the focus of this particular Guidance document. Within the DES QA System, such checking is ordinarily done within the affected program – that is, you check yourself. If someone from another program is available and an informal swapping of services can be done, this is preferable because checking one's own work in an unbiased fashion can be challenging.

The checking step must address the *root cause* of any deficiencies identified, wherever this is possible, so that procedures can be continuously improved. Most importantly, the checking process must be conducted regularly, and the results documented and tracked. It is important to understand that the purpose of the self-assessment process is to identify areas for improvement, not finding fault.

A self-assessment form is a very useful tool that helps to ensure that all critical program areas are adequately evaluated and addressed. Also, the form itself can be used to record and communicate the results of the self-assessment. The two primary self-assessment forms used for the Annual QA System Program Self-Assessments are discussed and presented below.

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4. DES QA System Self-Assessment Forms

The following pages include self-assessment forms that program managers can use to help them assess their program's QA system. These forms will be submitted to the DES QA Manager, Vince Perelli, by January 31 of every year. They should be signed by the program manager, but may be prepared by other staff, as the program manager decides. The completed form can serve as documentation that a program has complied with the self-assessment requirement and to communicate its results to the QA Manager and others. In this guidance, two self-assessment form options are available:

1. ***Form A*** is for DES programs whose operations using environmental data are described in one or more EPA-approved Quality Assurance Project Plans (QAPPs), or who have complete Quality Assurance Manuals.

2. ***Form B*** is intended for programs that are in the earlier stages of building a QA system. Form B consists of several sets of questions, each of which are specific to particular topics within the DES QA System. Each of them refers to a chapter or section of the DES Quality Management Plan. Program managers should only use the self-assessment form areas that apply to their programs – do not be afraid to write in "N/A," or write in a reference to another document, as you find applicable. Form B is also useful to help programs with

established quality systems to conduct a more complete self-assessment. As noted above, use of a form can ensure that all program areas are adequately covered.

The DES QA Team requires the use of either of these two forms, as opposed to other forms that program managers may have or produce. However, we are aware of the wide diversity among DES programs. Therefore, if you have an alternate form to report your annual program self-assessment, please send it to the DES QA Manager for review.

If you have questions, please refer to the QMP (available online at http://intranet/qa/plan.pdf), or contact the DES QA Manager, Vince Perelli (vperelli@des.state.nh.us), or a member of the DES QA Team (see http://intranet/qa/team.htm).

QA System Annual Program Self-Assessment -- *Form A*

Calendar Year 2003

(*Note: Please fill out one Self Assessment Form per program*)

Name of DES Program: _____

Bureau and Division of DES Program: _____

Name of Person(s) Conducting the Review: _____

1. I have a QAPP (Yes ☐ No ☐) and/or QA Manual (Yes ☐ No ☐) covering my program: (*If the answer is "No" to both questions, **Stop!** This form is not appropriate for your program – **Please use Form B***).

   Title of QA Document: _____
   Date of document: _____

   Has it been approved by ☐ EPA, ☐ Other organization/person – What/Who? _____
   - ➔ *Please attach a copy of cover and signature pages*.

   ☐ Other – Draft under review, not approved yet.

2. Every year, your multi-year QAPP/QA Manual must be reviewed and updated, as necessary. This is your report of the results of that review. Please attach the following:

   - ➔ A list of the non-conformances identified in the Calendar Year '02 (*i.e.,* last year's) review, and a description of how they were resolved;
   - ➔ A list of non-conformances identified in this year's review, and a schedule describing how you intend to address them. **Note:** When listing your non-conformances, please use the following convention: Year/Non-Conformance Number – 2003-01, 2003-02, 2003-03, etc.

3. Special questions for this year:

   A. Have you had any personnel changes? Yes ☐ No ☐
      - ➔ *If yes, please attach updated copies of the QAPP/QA Manual Distribution List and Program/Task Organization Sections.*

   B. Any changes in Special Training/Certification? Yes ☐ No ☐
      - ➔ *If yes, please attach updated copy of the Special Training/Certification Section.*

   C. Do you forward staff training records to DES Human Resources? Yes ☐ No ☐
      - ➔ *If no, please attach a description of how you keep these records.*

I certify that the DES program under my supervision is participating in the DES Quality Assurance System and that the above accurately reflects the Annual Self-Assessment of this program's QA System.

Program Manager Signature: _____

Printed Name: _____

Date: _____

QA System Annual Program Self-Assessment -- *Form B*

Calendar Year 2003

(***Note: Please fill out one Self Assessment Form per program***)

Name of DES Program: _____

Bureau and Division of DES Program: _____

Name of Person(s) Conducting the Review: _____

I certify that the DES program under my supervision is participating in the DES Quality Assurance System and that the above accurately reflects the Annual Self-Assessment of this program's QA System.

Program Manager Signature: _____
Printed Name: _____
Date: _____

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1. I have a QAPP (Yes ☐ No ☐) and/or QA Manual (Yes ☐ No ☐) covering my program: (*If the answer is "Yes" to either question,* ***Stop!*** *This form is not appropriate for your program –* ***Please use Form A***).

2. Every year, your program's QA efforts must be reviewed and updated, as necessary. This is your report of the results of that review. Please attach the following:

   - ➔ A list of the non-conformances identified in the Calendar Year '02 (*i.e.,* last year's) review, and a description of how they were resolved;

   - ➔ A list of non-conformances identified in this year's review, and a schedule describing how you intend to address them. **Note:** When listing your non-conformances, please use the following convention: Year/Non-Conformance Number – 2003-01, 2003-02, 2003-03, etc.

Note: When asked to "show/provide" documentation, a copy should be attached, unless the document in question is both a) book-length *and* b) readily available, (*e.g.* EPA guidance documents).

Do not hesitate to write N/A within a section or at the top of a page that doesn't apply to your program.

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1. Background Information

a) What data do you gather/use/compile?	
b) What decisions are made using these data?	

c) What is the audience for the data?	

2. Data Quality Objectives (DQOs)

Ref: DES QMP Sec 8.3

a) Show/provide documentation on how you determine your data quality needs or objectives. If none documented, describe them	
b) How are these data quality needs/objectives communicated to staff?	
c) Do your DQOs change when there are enforcement concerns?	

3. Sampling

Ref: DES QMP Sec.8.4

a) Show/provide written sampling procedures If none documented, describe them	
b) How do you field-modify sampling procedures? Show/provide approval procedures. How are changes approved? How are changes recorded? Provide documentation of field-modification	

guidance/procedures d) How are training records kept? Show/provide documentation	
e) How is equipment calibrated?	
f) How are calibration records kept?	
g) How do you ensure that your sampling methods and procedures meet your data needs?	

4. Field Testing **Ref: DES QMP Sec. 8.5**

a) Show/provide written field testing procedures If none documented, describe them	
b) How do you field-modify testing procedures? If non documented, describe them How are changes approved? How are changes recorded? Provide documentation of field-modification guidance/procedures	
c) How is staff trained in procedures?	
d) How are training records kept?	
e) How is equipment calibrated?	
f) How are calibration records kept?	

g) What field records are generated? Show/provide copy of guidance/procedure	
h) How are records kept in the office? Show/provide copy of procedure/guidance	
i) How do you ensure that your sampling methods and procedures meet your data needs?	

5. In-house Testing

Ref: DES QMP Sec. 8.6

Note: This is intended for DES programs that do at least some of their own testing. It is ***not*** intended for the Laboratory Services Unit, which has its own extensive QA Program. It is also ***not*** intended for programs or persons who take water or other samples and brings them to the DES Laboratory for testing.

a) What type of in-house testing do you use?	
b) What methods are used?	
c) How do you ensure that protocols are up to date?	
d) How do you check in-coming sample material?	
e) How are data handled when a test is not run per specification?	

f) How is staff trained? How are training records kept?	
g) Show/provide copy of procedure for recording test results	
h) Show/provide copy of procedure for communicating results to the data user?	

6. Environmental Conditions Descriptions & Data

Ref: DES QMP Sec. 8.7

a) How do you decide what information to record? Provide documentation of decision	
b) How is the information recorded? If forms, provide copies	
c) Show/provide copy of procedures for taking field notes? If none documented, describe them	
d) Show/provide copy of procedures or guidance for photo-documentation. If none documented, describe them	
e) How is staff trained? How are training records kept?	
f) How are deviations from procedures handled? Before the fact. After the fact.	

g) How are changes to procedures made? Who approves? How are they communicated to staff? Show/provide example document. Is there a procedure for this process?	

7. Review & Validation of Data **Ref: DES QMP Sec. 9.2**

a) Show/provide any written guidance you have to describe how you check data. If none documented, describe them.	
b) Show/provide any written guidance you have to describe how you address non-conforming data. If none documented, describe them.	

8. Retention of Data **Ref: DES QMP Chap. 6, esp. Sec 6.2**

a) Show/provide filing procedures. If none documented, describe them.	
b) Do you keep back-up copies of any data? How do you decide what to back-up? Show/provide copy of procedure.	
c) Show/provide procedures for securing files. If none documented, describe them	
d) How long do you retain data? Show/provide copy of data retention decision. Include data removal/ destruction decision.	

9. Reporting Results

Ref: DES QMP Sec. 8.8

a) Who do you send data to? *Note: "Send" refers to anyone outside of the program, whether elsewhere in DES, or external to DES*	
b) Show/provide written guidance on reporting formats. If none documented, describe them.	
c) How do you decide who is responsible for signing the data reports? Show documentation of decision.	
d) When reporting to different audiences, do you vary the form or type of report? How is this decision made?	
e) How is staff informed of proper reporting methods? Provide example documentation	

10. System Reviews & Assessments

Ref: DES QMP Chapters 9 & 10

a) Do you *periodically* review your data quality system to see that it is up to date and appropriate? Show/provide documentation for the last review. **Note:** This does not refer to ad hoc adjustments.	
b) How do you document and correct non-conformances?	